



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0535]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0374. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body--(OMB Control Number 0910-0374)--Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the Federal Register of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled “Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.” The guidance provides the Agency's interpretation of terms central to the submission of a notification and the Agency's views on the information that should be included in the notification. The Agency believes that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required

by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the Agency receives to ensure that they comply with the criteria established by the FD&C Act.

In the Federal Register of August 3, 2011 (76 FR 46819), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Section of the FD&C Act	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for notifications	2	1	2	1	2
Total					702

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, the Agency estimates that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. FDA estimates that it will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, FDA believes that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, FDA estimates that 1 respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, FDA estimates that 1 respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. FDA has determined that this information should be readily available to a respondent and, thus, the Agency estimates that it will take a respondent 1 hour to incorporate the information into each notification. The Agency expects there will be 2 respondents for a total of 2 hours.

Dated: December 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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